



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: D456181; **FILE SYMBOL No.:** 66222-EIO; **PRODUCT NAME:** Adm.07000.H.2.A;
ABN-Highcard; **DECISION No.:** 559279; **ACTION CODE:** R334.2; **FOOD Use:** Yes; **COMPANY:** Makhteshim
Agan of North America Incorporation

DATE OUT: November 30, 2020

SUBJECT: End Use Product Chemistry Review
Product Name: Adm.07000.H.2.A

FROM: Shyam Mathur, Ph. D *sbmathur* 11-30-2020
Product Chemistry Team Leader
CITAB / RD (7505P)

THROUGH: Kerry Leifer, Branch Chief
CITAB / RD (7505P)

KERRY LEIFER

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TO: Lydia Crawford / Emily Schmid, RM 25, Herbicide Branch / RD (7505P)

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product Adm.07000.H.2.A. The registrant has submitted a CSF for basic formulation (dated December 18, 2019) and the supporting product chemistry data with MRID No's. 51020901 to 51020906. CITAB has been asked to determine the acceptability of the proposed basic CSF and the supporting product chemistry data.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s):

Active Ingredient	Reg. No.	NC of AI in product	PC code
Quizalofop-P-Ethyl [REDACTED]	[REDACTED]	[REDACTED]	128709

2. Has the registrant claimed substantial similarity to a registered product?

[] Yes; [X] No; [] NA; if yes give the registration number of the cited product. EPA Reg. No:

3. All of the source materials of the active ingredient are derived from registered sources- [] Yes [X] No

Note: Source of the active ingredient with FSN: [REDACTED] is undergoing process of registration with the Agency.

4. All inert ingredients have been screened by CITAB (Inert group) and found to be approved for the proposed labeled uses.

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5. Confidential Statement of Formula(s):

☒ Basic - Dated: 12-18-2019; Re-submitted - Dated:

☐ Alternate CSF – Dated: ; Re-submitted alt CSF – Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredients)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☐ Yes ☒ NA:
acid equivalent =

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☒ Yes ☐ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite ☐ Yes ☒ No ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes; ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

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7. Group **A**: Product Chemistry Data submitted

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	51020901
830.1600	Description of materials used to produce the product		X		A	51020901
830.1650	Description of formulation process		X		A	51020901
830.1670	Discussion on the formation of impurities		X		A	51020901
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	Basic CSF dated 12-18-2019
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	51020901 51020902 HPLC-UV(240 nm & 254 nm) using external standard calibration method. The analytical method was validated for linearity, precision, accuracy, LOD& LOQ Method validation provided.

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

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8. Group B: Product chemistry data submitted

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Yellowish-red colored Liquid with characteristic odor at 20°C	A	51020902
830.6315	Flammability	107°C	A	51020904
830.6316	Explodability	Waiver request. TS is not formulated with ingredients that have the chemical bonds or functional groups associated with explosive chemicals.	A	51020906
830.7000	pH	7.0 to 5.9 (1% w/w suspension in water) at 25°C	A	51020902
830.7300	Density (units)	1.0491 g/ml (8.75 lbs/gal) at 20°C	A	51020902
830.7100	Viscosity	TS behaved like Newtonian liquid. Dynamic viscosity determined with shear rates from 20 s ⁻¹ to 100 s ⁻¹ Results: 12.0 mPa. s @ 20°C 6.0 mPa. s @ 40°C	A	51020905
830.6317	Accelerated Storage stability	TS was found to be stable with respect to AI contents, when stored in HDPE/PET-G packaging for 2 weeks at 54 deg C.	A	51020902
830.6320	Accelerated Corrosion characteristics	TS was stored in packaging of HDPE/PET-G for two weeks at 54°C. No change in packaging. No signs of deterioration or distortion of the packages were observed after storage. No significant change in weight. No visible interaction of the product with its packaging. There was no seepage through the container walls or lid. Non-corrosive to stainless steel, brass & Aluminium	A	51020902
830.6314	Oxidation/reduction	TS was found to be compatible with water, monoammonium phosphate, Zn powder and m-xylene, but was non-compatible with KMnO ₄	A	51020903

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CONCLUSIONS:

Note: Registration of the proposed end use product is contingent upon the registration of the source of the active ingredient with FSN: [REDACTED], which is under-going process of registration with the Agency.

CITAB has reviewed the product chemistry data submitted for the end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. No.) from Product chemistry view point

- ☐ Similar
- ☐ Not similar, give reasons:
- ☐ Identical
- ☐ Not identical
- ☒ Not Applicable
- ☐ Not Determined

B. Confidential Statement of formula

1. Basic CSF (dated: 12-18-2019)

- ☒ Acceptable
- ☐ Not Acceptable:
- ☐ Not Applicable

2. Alternate CSF (dated:)

- ☐ Acceptable
- ☐ Not Acceptable:
- ☒ Not Applicable

C. Group A Product Chemistry Data

- ☒ Acceptable
- ☐ Acceptable with the exception of the guideline:
- ☐ Not acceptable
- ☐ Not required
- ☐ Data cited for the guideline

D. Group B Product chemistry data

- ☒ Acceptable
 - ☐ Not acceptable
 - ☐ Acceptable with the exception of the guidelines
 - ☐ Not required
 - ☐ Data cited
 - ☒ Waiver requests: Acceptable ☒; Not Acceptable ☐; Not Applicable ☐
- For guidelines: 8306315, 830.6319 (miscibility), 830.6321 (DEB) & 830.7520 (particle size)

E. Product Label/Draft Label: Recommendations – Yes ☒; No ☐

Note to PM: Since the product was found to be incompatible with oxidizing agents, the registrant is recommended to add the following statement under Physical-Chemical Hazards on the product label:

“Do not mix or allow coming in contact with Oxidizing agents. Hazardous Chemical reaction may occur”

